UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM	Judge Patti B. Saris

MEMORANDUM OF SCHERING-PLOUGH CORPORATION IN SUPPORT OF THE MOTION TO DISMISS

Schering-Plough Corporation ("Schering") moves to dismiss the State of Montana's Second Amended Complaint ("Mont. Cplt.") and the State of Nevada's Amended Complaint ("Nev. Cplt.") (collectively the "Amended Complaints") pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). The States' allegations that Schering has reported fraudulently inflated average wholesale prices cannot stand in light of the States' own knowledge that average wholesale price is not the price that typically is paid. Moreover, the Amended Complaints fail to allege the factual predicates with respect to Schering drugs that this Court has already determined Rule 9(b) requires. Finally, the Amended Complaints provide no facts whatsoever to substantiate their claims that Schering misreported Best Price. For these reasons and the reasons set forth in the Consolidated Memorandum In Support Of Defendants' Motion To Dismiss The State Of Montana's Second Amended Complaint And The State Of Nevada's Amended Complaint (the

"Consolidated Memorandum") all claims against Schering in the Amended Complaints should be dismissed.

I. The State's Knowledge That AWP Was Merely a Sticker Price Defeats the Fraud-Based Claims as a Matter of Law

Montana and Nevada – like all states – have been warned for *decades* that AWP should not be used to establish reimbursement rates for state Medicaid programs. As detailed in the Consolidated Memorandum, the Office of the Inspector General ("OIG") of the Health Care Financing Administration ("HCFA") (now the Center for Medicare and Medicaid Services or "CMS") has warned states repeatedly that AWP is not a price that pharmacists and other purchasers of drugs actually pay. *See, e.g.*, HCFA Medicaid Transmittal, No. 84-12 (Sept. 1984) at 3 ("Pharmacies [actually] purchase drugs at prices that are discounted significantly below AWP or list price."); HS OIG Report, "Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program," (Oct. 1989), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 38,215 (1990) (noting that AWPs in industry publications overstate the prices that pharmacies actually pay by 10-20%). Indeed, HCFA formally disapproved the plans of those states that attempted to set Medicaid reimbursement rates at an undiscounted AWP. *Louisiana v. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990); *In re Arkansas Dep't of Human Servs.*, 1991 WL 634857 (HHS Dept. App. Bd. Aug 22, 1991); *In re Oklahoma Dep't of Human Servs.*, 1991 WL 634860 (HS Dept. App. Bd. Aug. 13, 1991). States have known for decades that AWP is not the price paid for prescription drugs.

The Amended Complaint confirms that, in setting their respective reimbursement rates, both Montana and Nevada acted with knowledge that AWP is not an actual price paid by providers. Montana reimburses at AWP-15%, and Nevada reimburses at AWP-10% plus a $4.76 dispensing fee. *See* Mont. Cplt. ¶ 162; Nev. Cplt. ¶ 126. In light of States' decision to reimburse

at a significant discount off AWP, the States cannot honestly claim that they believed AWP represented true wholesale prices for pharmacies, or that the publication of AWPs caused any actual harm to the States. It is readily apparent that the States' real claim is not that they were misled into believing that AWP represented actual wholesale prices, but that the States may have chosen the wrong discount off of AWP in estimating acquisition cost – a choice the States made without any input from manufacturers.

Given the States' admission that they *knew* that published AWPs were inflated and that they therefore *independently* established a reimbursement rate set at a discount off of AWP, their allegations of the "fraudulent reporting of false and inflated average wholesale prices" cannot state a claim as a matter of law.

II. All AWP-Based Claims Relating to Schering Should Be Dismissed for Failure to Meet the Pleading Requirements of Fed. R. Civ. P. 9(b).

Independent of the fatal flaws inherent in the States' multi-source theory, they have failed to meet the pleading requirements imposed by Fed. R. Civ. P. 9(b) and this Court's May 13 Order. In particular, the Court required that in this multidistrict litigation, plaintiffs state "(1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharma. Indus. AWP Litig.*, 263 F. Supp. 2d, at 194. Montana and Nevada have failed to allege a "fraudulent AWP" for *any* of the Schering drugs identified in the Amended Complaints.

Except in connection with Proventil®, the States fail to make a *single allegation* of specific conduct by Schering relating to the drugs identified in the Amended Complaints. *See* Nev. Cplt. ¶¶ 333-350; Mont. Cplt. ¶¶ 532-549. Instead, the Amended Complaints improperly seek to include Schering within generalized allegations of a "fraudulent scheme" among defendants to inflate AWPs "artificially," to provide free drug samples "improperly," and to

offer "other hidden and improper inducements." *See* Nev. Cplt ¶ 343, 392 ; Mont. Cplt. ¶¶ 542, 612. Such pleading, which includes Schering in an alleged "fraudulent scheme" while lacking particulars concerning the date, time or place of any alleged fraudulent representation or omission by Schering, does not satisfy Rule 9(b). *See Hayduk v. Lanna*, 775 F.2d 441, 444 (1st Cir. 1985) ("[M]ere allegations of fraud, corruption or conspiracy ... or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such accusations are repeated"); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001).

Regarding Proventil®, the States additionally allege only that "[a]t the generic launch of albuterol, Schering stated:

> Proventil will stay listed at AWP; therefore, Proventil is a favored product for third party reimbursement that provides for the AWP minus 10% reimbursement rate to chains. Thus, they can buy off the Proventil deal and bill at AWP."

Nev. Cplt ¶ 337; Mont. Cplt. ¶ 536. This statement, at most, confirms for Proventil the States' allegation that chains are reimbursed at "AWP, less a specified discount." It does not indicate that Proventil's published AWP – the only other fact regarding the drug that the States allege – was artificially inflated, or that the States did not know that the AWP for Proventil was not the drug's fully discounted price. Moreover, as with every Schering drug identified in the Amended Complaints, the States fail to allege the price they paid for Proventil. In fact, their own allegations suggest that they reimbursed the drug at an even greater discount off AWP than the one mentioned here. *See* Mont. Cplt. ¶ 162; Nev. Cplt. ¶ 126.. Schering's recognition that Proventil is reimbursed at "AWP minus 10%" thus adds nothing to the States' facile reproduction of Proventil's published AWP to explain how it was fraudulent.

The States cannot meet their burden of alleging a "fraudulent AWP" by simply identifying the published AWP without any explanation of how it is fraudulent or that it should have been lower. All claims against Schering should be dismissed for these independent reasons. *See, e.g., Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997).

III. **Montana's and Nevada's Allegations Concerning Best Price Reporting and Utilization of "Other Impermissible Inducements" Must Be Dismissed for Failure to Meet the Pleading Requirements of Fed. R. Civ. P. 9(b).**

Finally, the broad, general allegations that the defendants "did not report the actual Best Price or AMP" and "utilized other impermissible inducements to stimulate the sales of its drugs" are wholly without substance and should be dismissed in their entirety. Mont. Cplt. ¶¶ 542, 612; Nev. Cplt. ¶¶ 343, 392. Both States fail to provide a *single specific example* of a failure by Schering to report its statutory best price to CMS, or of any "impermissible inducements" allegedly offered by Schering to providers. These claims fail to state the requisite "who, what, where and how" of Schering's alleged fraud, s*ee United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001), and are insufficient under Rule 9(b) to "place [Schering] on notice and enable [it] to prepare meaningful responses." *New England Data Servs. v. Becher*, 829 F.2d 286, 289 (1st Cir. 1987).

CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum, Schering requests that it be dismissed from the Amended Complaints, and that the dismissal be with prejudice.

Respectfully Submitted,

Original Signature On File With Court

John T. Montgomery (BBO#352220)
Brien T. O'Connor (BBO#546767)
Crystal D. Talley (BBO#633759)
John R. Therien (BBO#651185)
Ropes & Gray LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000

Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Memorandum of Schering-Plough Corporation in Support of its Motion to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien